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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/642,638 | 08/19/2003 | Howard R. Levin | 3659-70 | 3724 |

23117 7590 11/08/2005

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| EXAMINER |
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DEAK, LESLIE R

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| ART UNIT | PAPER NUMBER |
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3761

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/642,638 | LEVIN ET AL. | |
| | Examiner | Art Unit | |
| | Leslie R. Deak | 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-71 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/15/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 55, 56, 60-62, 64-71, are rejected under 35 U.S.C. 103(a) as being unpatentable over a disclosure of the Hospal Miniflow 10 (see pages of internet data, accompanied by 1997 study from Gouyon et al, showing the existence of the Miniflow 10 as early as 1997), in view of US 5,246,582 to Sluma et al.

The Miniflow is disclosed and shown as having a hollow fiber surface area below 0.1m^2 , blood input and output lines with pump, and dialysis input and output lines with pumps (see CVVD illustration). The hollow fibers are arranged in a bundle in a straight housing (see diagram). The documentation does not disclose the dimensions of the housing, but the Miniflow appears to be less than 20cm long and less than 1.5cm in diameter. The Miniflow is also disclosed as being capable of use within a hemodialysis procedure, including the steps of flowing blood through the filter membrane in countercurrent to a dialysis fluid (see Hospal page entitled "Pump-assisted renal replacement therapies). Therefore, the Hospal filter apparatus is capable of being used in the method claimed by applicant.

The Miniflow documentation does not disclose the molecular weight of the molecules filtered, but Sluma discloses a filtration membrane that may have a screening

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coefficient for molecules of approximately 50,000 Daltons. The filter membrane is made with such small pore sizes in order to facilitate ultrafiltration (see column 3, lines 45-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the hollow-fiber filter membranes of the Hospal Miniflow 10 to block passage of molecules of about 50,000 Daltons as disclosed by Sluma in order to provide ultrafiltration, as taught by Sluma.

With regard to applicant's claims 61 and 69 drawn to the number of hollow fibers in the filter cartridge, it has been held that the duplication of the essential working parts of a device (in the instant case, a plurality of hollow fiber filters) involves only routine skill in the art. See MPEP 2144.04.

With regard to applicant's claim 66 drawn to the volume of the container comprising less than 2% of the patient's cardiac output, such a size limitation comprises an obvious variation of the device. See MPEP 2144.04. In the instant case, the Hospal cartridge capable of holding less than 2% of a patient's cardiac output, since patients of various size, which affects blood volume and cardiac output, may be treated by the device.

Similarly, applicant's claims 68 and 71 comprise limitations drawn to the length of the fibers and the diameter of the fiber bundle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to alter the size of the Miniflow to the dimensions desired by applicant since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. See MPEP 2144.04.

Allowable Subject Matter

3. Claims 57-59 and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
4. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the method as claimed by applicant. In particular, the prior art fails to suggest a method of ultrafiltration utilizing a filter membrane with the claimed surface area and claimed porosity wherein the filtrate and/or the blood is moved through the filter cartridge at the rates and within the times claimed by applicant.

Response to Arguments

5. Applicant's amendment filed 15 September 2005 has been entered and considered.
6. Applicant's arguments with respect to claims 55-71 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie Deak
Patent Examiner
Art Unit 3761
2 November 2005


PATRICIA BIANCO
PRIMARY EXAMINER
11/04/05